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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

JUL 14 2004

Applicant's or agent's file reference P26557PC00/TWI	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/00340	International filing date *(day/month/year)* 14.01.2003	Priority date *(day/month/year)* 14.01.2002
International Patent Classification (IPC) or both national classification and IPC C12N15/86		
Applicant VERENIGING VOOR CHRISTELIJK WETENSCHAPPELIJK ...		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14.08.2003	30.07.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Panzica, G Telephone No. +49 30 25901-328

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/00340

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-8, 10-55	as originally filed
9	filed with telefax on 18.06.2004

Claims, Numbers

1-23	filed with telefax on 22.04.2004

Drawings, Figures

1-12	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3, 5-9, 12,13
	No:	Claims	1, 2, 4, 10, 11, 14-23
Inventive step (IS)	Yes:	Claims	5-9, 12, 13
	No:	Claims	1-4, 10, 11, 14-23
Industrial applicability (IA)	Yes:	Claims	1-23
	No:	Claims	-

2. Citations and explanations

   see separate sheet

V. Reasoned Statement

The following documents are referred to in this report:

D1: WO 97 30732 A (ONYX PHARMA INC) 28 August 1997 (1997-08-28)
D2: WO 00 29573 A (CANJI INC) 25 May 2000 (2000-05-25)

1. Amendments (Art. 34.2.b PCT)

The present report is based on the set of claims received on 22.04.04. Amendments have been accepted as supported and in accord with the description as originally filed.

2. Novelty (Art 33.2 PCT)

2.1 Subject matter of claims 1, 2, 4, 10, 11, 14-23 is not new. D2 discloses conditionally replicating adenoviral vectors, based on Ad5 (e.g. human), able to restore the $p53^+$ phenotype into target cells, by the presence of a p53 gene under a CMV promoter, and to induce this way apoptosis into cells (see page 32 line 17, to page 34, line 15, and examples 1 and 2). D2 also discloses its use in a method of treatment, coresponding to claims 14-23.

3. Inventivity (Art. 33.3 PCT) and essential features (Rule 6.3 PCT))

3.1 Regarding claim 3, the use of the selectivity of the promoter to target neoplastic cells, avoiding infection and replication in non neoplastic cells, is also disclosed in D1 (see abstract, see page 5, line 19, to page 6, line 10; see page 11, line 11 to line 29).

3.4 In view of the above points, subject matter claims, 7-9, 12 and 13, which are novel, also appear to be inventive. Essential features present independent claims and in the disclosure of the application (see page 14 of the application, for instance) are not derivable from the prior art.

4. Further considerations for a later national/regional phase.

4.1 Expressions like "preferably" in the claims are not limiting the subject matter. Their use does not limit the scope of the claim to said feature (eg. "serotype 5" in claim 2)

4.2 Claims 21-23, relate to methods of treatment, a subject matter which is excluded from patentability by the European Patent Convention (see EPC Art.52.4).

4.3 A document published after the claimed priority date, (Van Beusechem et al. Cancer Res. 62, Nov. 2002, 6165-6171), has been introduced during the international examination. Priority document EP 1327688 is similar to the present application, but lacks i.a. examples 6-12 and subject-matter of claims 9 and 13.

4.4 Claims 5 and 6 refer to a "fuctional analogue". A protein or a compound can have a plurality of functions. In this regard, the definition of "functional analogue" is not clearly defined.